

inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Office Action states that although the limitations do not need to be verbally and exactly expressed in the specification, the limitations need to be discussed in the specification at some degree and that the newly added concept in the claim language "in the absence of material containing alcohol groups" is not explicitly discussed in the specification. Thus, the Office Action alleges that it constitutes new matter.

The amendment of the pending claims to recite the phrase "in the absence of material containing alcohol groups" does not constitute new matter and applicants respectfully request that this rejection be withdrawn. In particular, applicants wish to state the following in response to this rejection.

1) That applicants were in fact in possession of the embodiment of the invention as now claimed at the time this application was filed is apparent from a reading of the specification. Specifically, in every description of the invention set forth in applicants' disclosure, the reagents for separating single stranded and double stranded nucleic acid material are reagents that lack material containing alcohol groups. Furthermore, in each of the numerous examples provided in the specification on pages 6-17, chemicals and buffer compositions are described, every one of which lack material containing alcohol groups. Thus, it is readily and reasonably apparent to one skilled in the art that the specification demonstrates that the applicants were indeed in possession of methods of separating nucleic acids by employing liquids comprising chaotropic agents and nucleic acid binding solid phases in the absence of material containing alcohol groups.

Thus, applicants assert that, upon application of the appropriate standard for evaluating patent claims for adequate written description, it is apparent that the claims of the present invention meet this requirement. A review of the case law reveals that the courts have consistently held that it is well established that there is no *in haec verba* requirement and that newly added claim limitations can be supported in the specification through express, implicit, or inherent disclosure. (emphasis added). (see page 1105, first column of the Guidelines for

Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement as published on January 5, 2001 in the Federal Register (Vol. 66, pages 1099-1111). (emphasis added). In particular, the Court of Customs and Patent Appeals (CCPA) has stated that "[t]he function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter now claimed by him; how the specification accomplishes this is not material..... It is not necessary that the application describe the claim limitations exactly... but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that applicants invented processes including those limitations." (*In re Wertheim*, 541 F.2d 257 (CCPA 1976), citing *In re Smith*, 482 F.2d 910 (CCPA 1973) and *In re Smythe*, 480 F.2d 1379 (CCPA 1973).

In the same case quoted above, the CCPA also states that "...we must decide whether the invention appellants seek to protect by their claims is part of the invention that appellants have described as theirs in the specification. That what appellants claim as patentable to them is less than what they describe as their invention is not conclusive if their specification also reasonably describes that which they do claim. Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable."

In the present application, applicants previously presented claims to methods for separating single stranded nucleic acid from double stranded nucleic acid, comprising the steps of contacting a mixture comprising both single stranded nucleic acid and double stranded nucleic acid with a first liquid comprising a chaotropic agent and a nucleic acid binding solid phase, wherein the first liquid has a composition such that the double stranded nucleic acid binds to the solid phase; separating the solid phase from a supernatant containing the single stranded nucleic acid; and contacting the supernatant with a second liquid comprising a second nucleic acid binding solid phase, wherein the second liquid has a composition such that the resulting mixture of supernatant and second liquid allows for binding of the single stranded nucleic acid to the second solid phase. This earlier claim language contained no limitation that the steps of this

method be carried out in the absence of material containing alcohol groups and thus was broader in scope than the invention presently claimed. This broader embodiment of applicants' invention obviously met all of the written description requirements, because these claims was not rejected under 35 U.S.C. § 112, first paragraph in any previous Office Action.

What applicants are doing by presenting the currently claimed invention and what applicants are entitled to as demonstrated by the case law, is claiming as their invention a narrower embodiment of the broader invention that they have described in the specification. Applicants also wish to point out that in the present application, the inclusion of the limitation at issue does not present a different invention than what was claimed previously, it merely narrows the scope of the same invention. The CCPA has stated, in analyses of similar written description issues that "[w]here it is clear, for instance that the broad described range pertains to a different invention than the narrower (and subsumed) claimed range, then the broader range does not describe the narrower range. (*In re Wertheim*, citing *In re Baird*, 348 F.2d 974; *In re Draeger* 150 F.2d 572; see also *In re Eiselstein*, 52 F.3d 1035). This is clearly not the situation at hand, where the broader genus of methods clearly encompasses the presently claimed subgenus of methods employing reagents in the absence of materials containing alcohol groups and does not describe a different invention. Also, as stated above, the specification contains several examples of members of the subgenus of methods presently claimed with the limitation at issue, which are clearly recognized to be part of the invention as previously claimed and adequately described in the specification.

The case most closely in line with the facts of the present application is *Ex parte Parks* (30 USPQ2d 1234; copy enclosed), which is an opinion of the USPTO Board of Patent Appeals and Interferences. In *Purks*, claims were rejected under 35 U.S.C. § 112, first paragraph, for inadequate written description due to an amendment of the claims to include the recitation of the phrase "in the absence of a catalyst," which the Examiner alleged was a limitation that added new matter because this phrase lacked literal basis in the specification. In its analysis, the Board

cited several cases in support of the position that the observation of a lack of literal support does not, in and of itself, establish a *prima facie* case for a written description rejection.

The Board then cited *In re Anderson* as holding that "...it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed. (emphasis added). The Board ultimately determined that the written description rejection was improper on the basis of the following analysis.

In the situation before us, it cannot be said that the originally-filed disclosure would not have conveyed to one having ordinary skill in the art that appellants were in possession of the *concept* of conducting the decomposition step generating nitric acid in the absence of a catalyst. See, for example, column 5 of the '562 patent, first paragraph, wherein FIG. 4 is discussed. Pyrolysis temperatures of between 600°C and 700°C, and above 700°C were employed to achieve conversion of chemically bound nitrogen to nitric oxide. Smooth conversion was obtained above 700°C, while the optimum conversion was found to occur above 900°C. Throughout the discussion which would seem to cry out for a catalyst if one were used, no mention is made of a catalyst. (emphasis in the original).

Like the teachings of the specification at issue in *Ex parte Parks*, in which examples are provided that make no mention of a catalyst, the examples in the instant specification set forth the steps of the claimed methods with no mention of including materials containing alcohol groups. Thus, by applying the same reasoning as set forth by the Board in *Ex parte Parks*, it cannot be said that the instant specification as filed would not reasonably convey to one of ordinary skill in the art that applicants are in possession of the concept of the claimed methods including the limitation at issue and therefore meet the written description requirement of 35 U.S.C. § 112, first paragraph.

Thus, in posing the question of whether one of ordinary skill in the art would reasonably conclude, upon reading the specification of the present application, that the applicants were in possession of methods of separating single and double stranded nucleic acids by employing

reagents which lack alcohol groups, it must be concluded that the only answer to this question is yes. Stated in another way, it cannot be concluded, upon review of the teachings of the instant specification, that applicants did not possess methods of separating single and double stranded nucleic acids by employing reagents that lack alcohol groups.

For the reasons presented above, applicants have demonstrated that they have met the requirements of adequate written description for the invention as presently claimed and assert that no new matter is added by the limitations recited in the pending claims. For these reasons, applicants respectfully request the withdrawal of this rejection and allowance of the pending claims to issue.

2) In accordance with MPEP § 2163.04, entitled "Burden on the examiner with regard to the written description requirement," the Examiner bears "...the initial burden of presenting by a preponderance of the evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims." Specifically, this section of the MPEP states that the Examiner must establish a *prima facie* case by providing reasons supported by express findings of fact as to why one skilled in the art would not recognize that the inventor was in possession of the claimed invention in view of the disclosure of the application.

As evidenced by the rejection set forth in the present Office Action, the Examiner has failed to meet this burden. Specifically, the only reasoning provided by the Examiner as any basis for this rejection is that although the limitations need not be verbally and exactly expressed, the limitations introduced by applicants "...need to be discussed in the specification at some degree." The Examiner provides only the additional comment that "[t]he newly added concept in the claim language 'in the absence of material containing alcohol groups' is not explicitly discussed in the specification." The Examiner provides no findings of fact as evidence to support the position that one of ordinary skill in the art would fail to recognize that applicants were in possession of the invention as now claimed. Thus, if the Examiner maintains the present

Attorney Docket No. 9310.28CT

In re: Goudsmit et al.

Serial No.: 09/760,085

Filed: January 12, 2001

For the foregoing reasons, applicants believe that all of the pending rejections have been adequately addressed and that the claims as presented are in condition for allowance. The Examiner is encouraged to contact the undersigned directly if such contact will expedite the examination and allowance of the pending claims.

No fee is believed due. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,



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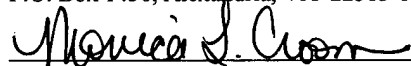
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Creation date: 11-17-2003
Indexing Officer: NIFILL - NICOLE IFILL
Team: OIPEBackFileIndexing
Dossier: 09760085

Legal Date: 07-11-2003

No.	Doccode	Number of pages
1	CTAV	5

Total number of pages: 5

Remarks:

Order of re-scan issued on